

Amendment Dated **December 9, 2003**

Amendment in Reply to Office Action Dated September 9, 2003

**REMARKS**

Claims 1-48, 50-52 and 54-104 are pending in this application with claims 1, 4, 5, 15-26, 29-38, 42-48, 54-80 and 89-104 being withdrawn from consideration. Claims 49 and 53 are canceled without prejudice or disclaimer of the subject matter therein and claims 9-14, 20-26, 56-62, 75, 84-88 and 90-93 are amended. Further, Applicants' elected "Species" is drawn to reducing temperature, where claims 2, 3, 6-14, 27, 28 and 82-88 are generic and claims 49-53 and 81 are directed to the elected "Species."

**I. Information Disclosure Statement**

Submitted herewith is a copy of a postcard noting that the Information Disclosure Statement filed on April 5, 2002 was filed with copies of the references. The Information Disclosure Statement was filed with a legible copy of each U.S. and foreign patent. Consideration of the Information Disclosure Statement and the references therein is respectfully requested.

**II. 35 U.S.C. § 112, Second Paragraph**

The Office Action rejects claims 49 and 53 under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit that the above amendments obviate this ground of rejection. Withdrawal of the rejection is respectfully requested.

**III. 35 U.S.C. § 102(b)**

The Office Action rejects claims 2, 3, 27, 28, 39-41, 50-52 and 81-88 under 35 U.S.C. § 102(b) over Campalani et al. (hereinafter Campalani) "Aortic Valve Replacement With Frozen Irradiated Homografts," European Journal of Cardiothoracic Surgery, 1989. Since Campalani fails to disclose or suggest all of the features of the claims, the rejection is respectfully traversed.

Applicants respectfully submit that Campalani fails to disclose or suggest, as recited in claim 2, at least the feature of reducing the temperature of one or more heart valves to a level effective to protect the one or more heart valves from radiation and irradiating the one or more heart valves with a suitable radiation at an effective rate for an effective time to sterilize the one or more heart valves. Rather, Campalani does not disclose or suggest reducing the temperature of one or more heart valves to a level effective to protect the heart valves from irradiation.

Campalani discloses that homografts were soaked, then double bagged and frozen to -70°C by emerging in liquid nitrogen. Then, within a few days, they were sterilized by 2.4 megarads of gamma irradiation and, thereafter, stored at -70°C until their use.

Campalani does not disclose reducing the temperature of one or more heart valves to a level effective to protect the heart valves from the irradiation. Rather, Campalani does not disclose or suggest the temperature of its homographs during irradiation, let alone reducing

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the temperature to a level effective to protect the heart valves from the radiation, as presently claimed.

Similarly, with respect to claim 3, Campalani fails to disclose or suggest reducing the temperature of one or more heart valves and irradiating the one or more heart valves with a suitable radiation at an effective rate for a time effective to sterilize the one or more heart valves, wherein the reduction in temperature and the rate of irradiation are together effective to protect the one or more heart valves from the radiation.

For at least the reasons set forth above, Applicants respectfully submit that claims 2 and 3 are allowable. Claims 27, 28, 39-41, 50-52 and 81-88 depend from claims 2 or 3 and are allowable for at least the same reasons as claims 2 or 3. Withdrawal of the rejection is respectfully requested.

**IV. 35 U.S.C. § 103(a)**

The Office Action rejects claims 2, 3, 6-14, 27, 28, 39-41, 49-53 and 81-88 under 35 U.S.C. § 103(a) over Campalani in view of Dziedzic-Goclawska et al. (hereinafter “the Dziedzic-Goclawska reference”), “Advances in Tissue Banking,” Vol. I. Since the references, alone or in combination, fail to disclose or suggest all the features of the claims, the rejection is respectfully traversed.

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Applicants respectfully submit that for the reasons discussed above, Campalani does not disclose or suggest all of the features of the claims. The Dziedzic-Goclawska reference fails to cure the deficiencies of Campalani. Similar to Campalani, the Dziedzic-Goclawska reference does not disclose or suggest reducing the temperature of one or more heart valves to protect the heart valves from radiation.

For at least the reasons set forth above, Applicants respectfully submit that all pending claims are in condition for allowance. Withdrawal of the rejection is respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney Laura L. Lee, at the telephone number listed below.

Serial No. 10/024,043

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To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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